

20-04-2001

IB 000000100

CLAIMS

1. A method for cancer diagnosis or prognosis which comprises:
 - (a) treating a sample from a human or animal subject with a solid phase under conditions to bind telomerase to the solid phase;
 - (b) separating the solid phase from the treated sample to form a test sample which is optionally treated to elute bound telomerase from the solid phase; and
 - (c) assaying the test sample for telomerase activity,wherein detection of telomerase activity in the sample is indicative of cancer in the subject.
2. A method according to claim 1, wherein the solid phase is assayed for telomerase activity in step (c).
3. A method according to claim 1 or claim 2, wherein the sample comprises target whole cells, which are treated in step (a) to form a lysate to release telomerase for binding to the solid phase.
4. A method according to claim 3, wherein the sample comprising the target whole cells comprises a mixture of cell populations which is subjected to a sorting step before step (a) to isolate the target whole cells in the sample.
5. A method according to claim 4, wherein the sorting step comprises flow cytometry sorting or a step of binding the target whole cells to a solid phase affinant for the target whole cells.
6. A method according to claim 5, wherein the affinant is present on the solid phase for binding the telomerase.
7. A method according to claim 5 or claim 6, wherein the affinant comprises an antibody specific to the target cells.

20-04-2001

IB 000000100

8. A method according to any one of claims 5 to 7, wherein the affinant is specific for epithelial cells.
9. A method according to any one of claims 4 to 8, wherein the mixture of cell populations is from blood, bone marrow, a pleural effusion, urine, saliva, sputum, faeces, spinal fluid, a cervical smear, a buccal swab, or a needle biopsy sample.
10. A method according to claim 9, wherein detection of telomerase activity in the sample is further indicative of micrometastasis in the subject.
11. A method according to any one of the preceding claims, wherein the solid phase comprises a particulate material.
12. A method according to claim 11, wherein the particulate material comprises polymeric beads.
13. A method according to claim 12, wherein the polymeric beads have a diameter in the range of from 1μ to 6μ m.
14. A method according to any one of claims 11 to 13, wherein the particulate material is magnetic.
15. A method according to any one of the preceding claims, wherein the step (c) of assaying for telomerase activity uses a telomeric repeat assay protocol.
16. Use of a solid phase for detecting telomerase activity in a sample by treating the sample with the solid phase so as to bind the telomerase thereto and assaying the solid phase for telomerase activity.

20-04-2001

IB 000000100

17. Use of a solid phase according to claim 18, in a method according to any one of claims 1 to 15.
18. Use of a kit for detecting telomerase activity, wherein the kit comprises a solid phase for binding telomerase, and one or more components for assaying for telomerase activity, and wherein the solid phase is used to bind telomerase.
19. Use according to claim 18, wherein the solid phase comprises a particulate material.
20. Use according to claim 19, wherein the particulate material comprises polymeric beads.
21. Use according to claim 20, wherein the polymeric beads have a diameter in the range of from 1 μm to 6 μm .
22. Use according to any one of claims 19 to 21, wherein the particulate material is magnetic.
23. A kit for detecting telomerase activity, comprising a solid phase for binding telomerase and one or more components for assaying for telomerase activity, wherein the solid phase comprises an affinant for binding target whole cells.
24. A kit for detecting telomerase activity, comprising a solid phase for binding telomerase and one or more components for assaying for telomerase activity, which further comprises a second solid phase for binding target whole cells.
25. A kit according to claim 24, wherein the second solid phase comprises an affinant for binding target whole cells.
26. A kit according to claim 23 or claim 25, wherein the affinant comprises an antibody specific to the target cells.

20-04-2001

IB 000000100

27. A kit according to any one of claims 23, 25 or 26, wherein the affinant is specific for epithelial cells.
28. A kit according to any one of claims 23 to 27, wherein the one or more components for assaying telomerase activity comprise a substrate for telomerase elongation.
29. A kit according to claim 28, wherein the substrate for telomerase elongation is present on the solid phase for binding telomerase.
30. A kit according to any one of claims 23 to 29, wherein the one or more components for assaying telomerase activity comprise components for a telomeric repeat assay protocol.
31. A kit according to any one of claims 23 to 30, wherein the one or more components for assaying telomerase activity include oligonucleotide primers to amplify the telomerase product.
32. Use of a kit according to any one of claims 23 to 31, for the detection of cancer cells.
33. Use according to claim 32, wherein the kit further comprises means for assaying an mRNA diagnostic for cancer.